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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,292	01/29/2004	Joan S. Steffan	51880/CAB/R2682	6474

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	
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06/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,292	STEFFAN ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are presented for examination.

Requirement for Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5-10, drawn to a method for treating polyglutamine expansion related neurodegeneration or a method for treating Huntington's disease comprising oral administration of a deacetylase inhibitor, classified in class 514, subclasses 10 or 296, depending on the inhibitor used.

II. Claims 11-13, drawn to a method for treating Parkinson's disease comprising oral administration of a deacetylase inhibitor, classified in class 514, subclasses 10 or 296, depending on the inhibitor used.

III. Claims 14-16, drawn to a method for treating amyotrophic lateral sclerosis, classified in class 514, subclasses 10 or 296, depending on the inhibitor used.

Claims 1-4 link Inventions I-III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-4. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are not longer applicable. Please reference *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). Please also reference MPEP §801.01.

Inventions I-III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. Please reference MPEP § 806.05(j).

In particular, Inventions I-III are related because they recite the oral administration of a therapeutically effective amount of a deacetylase inhibitor. However, the therapeutic objective(s) of each of Inventions I-IIII are unique and distinct from one another such that the patient populations treated via each of the methods does not necessarily overlap in scope with any one or more of the other claimed inventions.

Further, Inventions I-III comprise steps that are not required for any other method because each expressly recites the administration of an amount effective to achieve the claimed therapeutic purposes. In other words, the amounts required to achieve each objective are distinct and unique to the desired objective.

Accordingly, the modes of operation, functions and/or effects of the methods are clearly distinct from one another, despite the fact that the Inventions are related solely on the basis of the oral administration of a therapeutically effective amount of a deacetylase inhibitor. In view of the fact that the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants, the inventions are properly held to be patentably distinct from one another.

Because these inventions are distinct for the reasons given above and they have acquired a separate status in the art because of their recognized divergent subject matter, the requirement for election for examination purposes as indicated is proper.

Election of Species Requirement

This application contains claims directed to patentably distinct species of:

(i) polyglutamine expansion related neurodegenerative disease (claims 5 and 8), and

(ii) deacetylase inhibitors (claims 2-4, 6-7, 9-10, 12-13 and 15-16).

The species are independent and/or distinct for the following reasons:

Regarding the species of polyglutamine expansion related neurodegenerative diseases, the species are independent or distinct because such diseases as recited in the present claims for which the amount of the deacetylase inhibitor must be therapeutically effective are each distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of active agent, frequency of treatment, etc.) and patient population such that a comprehensive search for the claimed compound in an amount effective to treat, for example, Huntington's disease, would not necessarily anticipate, suggest or render obvious the administration of the same or different compound in an amount effective to treatment an etiologically and pathophysiologically distinct disorder, such as spinocerebellar ataxia. Notwithstanding that Applicant may have established an underlying commonality to this genus of disorders, namely that each is associated with polyglutamine expansion, it remains that the art does not necessarily recognize such a shared characteristic as being common to the entire genera of neurodegenerative diseases encompassed by the claim, nor does the art necessarily recognize each as amenable to the same type of pharmacologic therapy. Each is considered patentably distinct from the others because the patient populations, dosage amounts and therapeutic protocol for treating neurodegenerative diseases are each unique to the type of disorder being treated such that a comprehensive search for the claimed compound in an amount effective for the treatment of a particular neurodegenerative disease in the prior art would not necessarily encompass a comprehensive search of the patent or non-patent literature for the claimed compound in an amount effective for the treatment of any one or more other neurodegenerative diseases.

Regarding the species of deacetylase inhibitor(s), the claimed inhibitors encompass such a breadth of compounds that are structurally and/or chemically distinct from any one single other

compound encompassed by the claimed formula and/or claimed species of inhibitor such that a comprehensive search of the patent and non-patent literature for any one compound would not necessarily result in a comprehensive search of any one or more of the other inhibitors. In consideration of the number and significant chemical and structural variability of deacetylase inhibitors actually claimed by the instant genera, the disparate nature and breadth of inhibitors encompassed by the claimed genera precludes a quality examination on the merits, not only because a burdensome search would be required for the entire scope of the claim(s), but also because the consideration of the findings of such a search for compliance with the statutes and requirements set forth under 35 U.S.C. 101, 102, 103 and 112, would be unduly onerous. Further, though Applicant has recognized a common functionality to the claimed compounds, e.g., that they are inhibitors of deacetylase, it remains that the art does not necessarily recognize such a function as being shared by the entire claimed genera of inhibitors and, as a result, does not necessarily recognize their equivalency or interchangeability. Additionally, it also remains that the art may recognize an advantageous use for the compound in achieving the presently claimed objective that is not necessarily tied to its function as a deacetylase inhibitor.

Election of Invention I requires Applicant to make the following species elections:

(i) Election of a **single disclosed specie** of polyglutamine expansion related neurodegenerative disease from those specifically claimed (see, e.g., claim 8) **or** those specifically disclosed (see, e.g., p.34, l.5-p.35, l.2) **or** a generic polyglutamine expansion related neurodegenerative disease not specifically claimed or disclosed; **and**

(ii) Election of a **single disclosed specie** of deacetylase inhibitor from those specifically claimed (see, e.g., claims 2-4, 6-7 or 9-10) **or** a generic deacetylase inhibitor not specifically claimed in present claims 2-4, 6-7 or 9-10.

Election of Inventions II or III requires Applicant to make the following species elections:

(iii) Election of a **single disclosed specie** of deacetylase inhibitor from those specifically claimed (see, e.g., claims 2-4, 12-13 or 15-16) **or** a generic deacetylase inhibitor not specifically claimed in present claims 2-4, 12-13 or 15-16.

Applicant is cautioned that the election of a particular specie of polyglutamine expansion related neurodegenerative disease or deacetylase inhibitor, wherein the elected specie(s) is/are not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

Currently, claims 1-9, 11-12 and 14-15 are generic.

Applicant is advised that a reply to this requirement is REQUIRED to include an identification of the single disclosed species of deacetylase inhibitor [which must also include a structural depiction and identification of each moiety present in the core chemical structure if Applicant elects a compound of Formula (I) as presented in instant claim 2] and, if applicable, an identification of the single disclosed species of polyglutamine expansion related neurodegenerative disease, that is elected consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though this requirement be traversed (37 C.F.R. 1.143) and

(ii) an identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

June 12, 2007

6/16/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER